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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/740,191      | 12/19/2000  | Liang-Chang Dong     | ARC 2556N1          | 7458             |

7590

05/06/2002

ALZA Corporation  
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Mountain View, CA 94043-7210

EXAMINER

SHEIKH, HUMERA N

ART UNIT PAPER NUMBER

1615

DATE MAILED: 05/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.



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|                                 |             |   |                     |
|---------------------------------|-------------|---|---------------------|
| APPLICATION NO./<br>CONTROL NO. | FILING DATE | FIRST NAMED INVENTOR /<br>PATENT IN REEXAMINATION | ATTORNEY DOCKET NO. |
|---------------------------------|-------------|---|---------------------|

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| EXAMINER |
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| ART UNIT | PAPER |
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11

DATE MAILED:

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

The Response filed 01/22/02 does not address the Office Action mailed 04/23/01.  
A courtesy copy of the Office Action and PTO-892 is enclosed.

## DETAILED ACTION

Acknowledgement is made of the Revocation/Power of Attorney and the Prior Art filed 04/20/01 and the Extension of Time (3 months), the Revocation/Power of Attorney and the Amendment, all filed 01/22/02.

The Response filed 01/22/02 does not properly address the Office Action mailed 04/23/01.

A courtesy copy of the Office Action and the PTO-892 are enclosed.

The reply filed on 01/22/02 is not fully responsive to the prior Office Action because of the following omission(s) or matter(s):

The Response does not address the appropriate rejections given in the Office Action. The applicants responded to 35 U.S.C. 112 Rejections, which were not made in the Non-final Office Action. In addition, a Response to 35 U.S.C. 102 Rejections was omitted. Furthermore, applicants responded regarding prior art references (Edgren et al., Oshlack et al., Baichwal and Svastano et al.), which were never used by the Examiner in the Office Action. See 37 CFR 1.111. Since the above-mentioned reply appears to be *bona fide*, applicant is given **ONE (1) MONTH or THIRTY (30) DAYS** from the mailing date of this notice, whichever is longer, within which to supply the omission or correction in order to avoid abandonment. **EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).**

### **Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600



UNITED STATES DEPARTMENT OF COMMERCE

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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
|-----------------|-------------|----------------------|---------------------|

09/740,191 12/19/00 DONG

L ARC 2556N1

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MOUNTAIN VIEW CA 94043-7210

HM12/0423

EXAMINER

MCQUEENEY, P

ART UNIT

PAPER NUMBER

1615  
DATE MAILED:

04/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

|                              |                               |                             |  |
|------------------------------|-------------------------------|-----------------------------|--|
| <b>Office Action Summary</b> | Application No.<br>09/740,191 | Applicant(s)<br>DONG ET AL. |  |
|                              | Examiner<br>P. E. McQueeney   | Art Unit<br>1615            |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2000.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 12-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 12-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- |  |  |
|--|--|
| 15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                     | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 16) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____    | 20) <input type="checkbox"/> Other:  |

### DETAILED ACTION

1. Acknowledgement is made of applicants' preliminary amendment filed December 19, 2000.

#### ***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

2. Claim 1 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of prior U.S. Patent No. 6,174,547 B1. This is a double patenting rejection.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 12, 14, 17, 18, 20 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Eckenhoff *et al.* (US 4,663,148). Eckenhoff *et al.* disclose a dispenser for

delivering a beneficial agent to an environment of use. Eckenhoff *et al.* disclose in claim 1 a dispenser compris[ing]:

- (a) a container comprising a gelatin cap and body [read capsule];
- (b) a composition compris[ing] a beneficial drug and a temperature sensitive means for forming a dispensable composition in a biological environment selected from the group consisting of a butter, wax, stearate, hydrogenated oil, partially hydrogenated oil, glyceride, glycol, ester and polyether [read liquid drug layer comprising a drug and a member selected from the group consisting of a mono- and di-glyceride];
- (c) means in the container for occupying an increasing volume in the compartment [read expandable layer which expands upon contact with fluid];
- (d) a wall surrounding the container comprising at least in part a semipermeable composition;
- (e) at least one passageway in the dispenser.

Eckenhoff *et al.* disclose at col. 8, line 62 through col. 10, line 14 the ingredients that make up the semipermeable wall. Eckenhoff *et al.* disclose at col. 10, line 15 through col. 11, line 34 the ingredients that make up the swellable, expandable inner member, including polymeric materials and osmagents. Eckenhoff *et al.* disclose at col. 11, line 35 through col. 12, line 45 the ingredients that make up the temperature sensitive means which includes surfactants and mono- and di-glycerides. These disclosures meets the limitations of applicants' claims 12, 14, 17, 18, 20 and 23.



4. Claims 12-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Wong *et al.* (US 5,324,280). Wong *et al.* disclose an osmotic system for delivering a beneficial formulation to an environment of use. Wong *et al.* disclose in claim 1 an osmotic system comprising:

- (a) a capsule;
- (b) a dosage amount of a beneficial agent liquid formulation;
- (c) an osmagent composition;
- (d) a semipermeable composition;

(e) at least one orifice that communicates with the exterior and the lumen. Wong *et al.* disclose the ingredients that make up the beneficial agent liquid formulation at col. 10, line 60 through col. 12, line 47 (active agents), col. 12, line 48 through col. 13, line 22 (mono- and di-glycerides and surfactants). This disclosure meets the limitations of applicants' claims 12, 14, 16-18, 20, 22 and 23. Wong *et al.* disclose in examples 1, 6-8 and 7 a wall-forming semipermeable composition compris[ing] cellulose acetate and polyethylene glycol. This disclosure meets the limitations of applicants' claims 15 and 21. Wong *et al.* disclose at col. 8, line 48 through col. 10, line 2 the ingredients that make up the hydro-activated layer, including osmopolymers and osmagents. Wong *et al.* disclose in example 10 an osmotic composition comprising polyvinylpyrrolidone and hydroxypropylmethylcellulose. This meets the limitations of applicants' claims 13 and 19.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 12, 14, 17, 18, 20 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eckenhoff *et al.*

Eckenhoff *et al.* disclose applicants' instant invention. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make a dispenser for dispensing a beneficial drug composition to a biological environment of use based on the teachings of Eckenhoff *et al.* The expected result would be a thermo-responsive, hydrophobic composition comprising insoluble to soluble drugs and which thermo-responsive composition in response to the temperature of the biological environment changes its form and becomes fluid, semisolid, or the like for enhanced delivery from the dispenser (col. 2, lines 43-49).

6. Claims 12-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong *et al.*

Wong *et al.* teach applicants' instant invention. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make an osmotic system for delivering at a controlled rate a beneficial agent formulation to a fluid environment of use based on the teachings of Wong *et al.* The expected result would be an osmotic system manufactured in the form of an osmotic device for delivering in vivo a beneficial liquid drug formulation, such as a lipophilic drug formulation, that is difficult to deliver (col. 2, lines 15-21).

7. Claims 12-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong *et al.*, as discussed above.

Wong *et al.* use the same ingredients as contained in applicants' membrane in their semipermeable composition. Wong *et al.* do not disclose the temperature at which their semipermeable composition softens. It is the position of the examiner that the semipermeable composition of Wong *et al.* softens at the same temperature of applicants' membrane because the ingredients are the same.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. E. McQueeney whose telephone number is 703-306-5827. The examiner can normally be reached on M, T, H, F 7:45 AM to 6:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-3592 for regular communications and 703-308-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

pem  
April 20, 2001

  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

**Notice of References Cited**

Application/Control No.

09/740,191

Applicant(s)/Patent Under  
Reexamination  
DONG ET AL.

Examiner

P. E. McQueeney

Art Unit

1615

Page 1 of 1

**U.S. PATENT DOCUMENTS**

| * |   | Document Number               |  | Date<br>MM-YYYY | Name             | Classification |    |
|---|---|-------------------------------|--|-----------------|------------------|----------------|----|
|   |   | Country Code-Number-Kind Code |  |                 |                  |                |    |
|   | A | US-4663148-A                  |  | 05-1987         | Eckenhoff et al. | --             | -- |
|   | B | US-5324280-A                  |  | 06-1994         | Wong et al.      | --             | -- |
|   | C | US-6174547-B1                 |  | 01-2001         | Dong et al.      | --             | -- |
|   | D | US- -                         |  |                 |                  |                |    |
|   | E | US- -                         |  |                 |                  |                |    |
|   | F | US- -                         |  |                 |                  |                |    |
|   | G | US- -                         |  |                 |                  |                |    |
|   | H | US- -                         |  |                 |                  |                |    |
|   | I | US- -                         |  |                 |                  |                |    |
|   | J | US- -                         |  |                 |                  |                |    |
|   | K | US- -                         |  |                 |                  |                |    |
|   | L | US- -                         |  |                 |                  |                |    |
|   | M | US- -                         |  |                 |                  |                |    |

**FOREIGN PATENT DOCUMENTS**

| * |   | Document Number               |  | Date<br>MM-YYYY | Country | Name | Classification |  |
|---|---|-------------------------------|--|-----------------|---------|------|----------------|--|
|   |   | Country Code-Number-Kind Code |  |                 |         |      |                |  |
|   | N | - -                           |  |                 |         |      |                |  |
|   | O | - -                           |  |                 |         |      |                |  |
|   | P | - -                           |  |                 |         |      |                |  |
|   | Q | - -                           |  |                 |         |      |                |  |
|   | R | - -                           |  |                 |         |      |                |  |
|   | S | - -                           |  |                 |         |      |                |  |
|   | T | - -                           |  |                 |         |      |                |  |

**NON-PATENT DOCUMENTS**

| * |   | Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages) |
|---|---|---|
|   | U |   |
|   | V |   |
|   | W |   |
|   | X |   |

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.